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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,088	10/10/2006	Shigenori Kuga	MNA-001	4709

31281 7590 03/31/2009
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EXAMINER	
LAU, JONATHAN S	

ART UNIT	PAPER NUMBER
1623	

MAIL DATE	DELIVERY MODE
03/31/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/578,088	KUGA ET AL.	
	Examiner	Art Unit	
	Jonathan S. Lau	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *8-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12 Jan 2009 has been entered.

This Office Action is responsive to Applicant's Remarks, filed 27 May 2008.

This application is the national stage entry of PCT/JP05/07349, filed 08 Apr 2005; and claims benefit of foreign priority document JAPAN 2004-132880, filed 28 Apr 2004; currently an English language translation of this foreign priority document has not been filed.

Claims 1-14 are pending in the current application. Claims 8-14, drawn to non-elected inventions, are withdrawn.

The following rejections are reiterated and maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Amended claims 1-5 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by McCandliss et al. (US Patent 4,536,207, issued 20 Aug 1985, of record) as evidenced by Falini et al. (Tissue Engineering, 2004, vol 10, p1-6, of record).

McCandliss et al. discloses a naturally occurring chitin-protein complex (column 1, lines 13-14). McCandliss et al. discloses the material is prepared from suitable chitin-containing material biomass raw material, for example mollusks (column 5, lines 38-43). As evidenced by Falini et al., chitin from mollusk shells is in the form of β-chitin, sandwiched between protein layers to form an inclusion complex (page 2, left column, lines 8-13). Falini et al. discloses the chitin-protein complex to exist as "intralamellar sheets", or sheets having a laminar structure meeting the definition of an intercalation compound (definition of "intercalation compound", IUPAC Gold Book, of record). McCandliss et al. discloses the complex dried at 100 °C, indicating it has a melting point of at least 100 °C, meeting limitations of instant claim 1. It is inherent that a protein is an organic compound, meeting limitations of instant claim 2, that contains at least oxygen and nitrogen, meeting limitations of instant claim 3, in the form of carboxyl and amino groups, and amide bonds, meeting limitations of instant claims 4 and 5. McCandliss et al. discloses the protein functions as an antibiotic with nematostatic and nematocidal activity (column 4, lines 20-22), meeting limitations of instant claim 7.

Claims 1-5 and 7, reciting "A manufactured β-chitin complex..." define said β-chitin complex in terms of a product-by-process in that said complex is the product of a manufacturing process. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.). See MPEP 2113. It is apparent from what is disclosed that the natural product produced by biological processes disclosed by McCandliss et al. produces a product that is identical or substantially identical to the instant invention as defined in the claim.

Response to Applicant's Remarks:

Applicant's Remarks, filed 12 Jan 2009, have been fully considered and found not to be persuasive.

Applicant asserts that the guest compound of the instant invention is a small polar molecule. However, no limitation regarding the molecular weight or size of the guest compound is found in the claims. The invention as disclosed in the instant claims encompasses macromolecular guest compounds such as the protein layers disclosed by McCandliss et al.

Applicant remarks that the Falini et al. describes a structure on a macro scale compared to the structure recited in Applicant's claims. However, TEM is well known in the art to be able to resolve images down to the Angstrom level, or the atomic scale. Rousseau et al. (Biomaterials, 2005, 26, p6254-6262, cited in PTO-892) provides evidence that the organic material responds like a single crystal (p6260, section 4. Concluding remarks), suggesting the structure is at the atomic scale, not a macro scale compared to the chitin layers. As this material exists as a continuous organic matrix and not a single crystalline layer, this disclosure implicitly discloses multiple layers in which the sandwiching of β-chitin between protein layers, or conversely the sandwiching of protein layers between β-chitin layers forms an inclusion complex that is encompassed by the instant invention as disclosed in the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drohan et al. (US Patent 6,124,273, issued 26 Sep 2000, of record) in view of Kim et al. (Journal of Polymer Science: Part B: Polymer Physics, 1996, 34, p2367-2374, of record).

Drohan et al. discloses a supplemented chitin hydrogel (column 6, lines 25-27) wherein the chitin serves as a carrier vehicle for "growth factors, analgesics, antimicrobial compositions, anti-inflammatory compounds, antibodies, anticoagulants, antiproliferatives, cytokines, cytotoxins, chemotherapeutic drugs, interferons, hormones, hydroxyapatite, lipids, oligonucleotides, osteoinducers, polymers, polysaccharides, proteoglycans, polypeptides, protease inhibitors, proteins (including plasma proteins), steroids, vasoconstrictors, vasodilators, vitamins, minerals, stabilizers and the like, for a prolonged period of time" (column 9, lines 35-45), meeting a limitation of instant claim 7. Drohan et al. discloses "supplemented" to mean the supplementary compound, or guest compound, may be mixed with the chitin components in liquid form prior to hydration or

added to the hydrogel as the matrix sets up after hydration (column 12, lines 24-26) and a "matrix" to mean the structural properties or architecture of a solid or semi-solid (including a hydrogel) in which other components may be cast, mixed, dispersed or dissolved (column 12, lines 55-58). It is inherent that a polysaccharide is an organic compound, meeting a limitation of instant claim 2, that contains at least oxygen, meeting a limitation of instant claim 3, in the form of hydroxyl groups and ketal bonds, meeting a limitation of instant claim 4, and that it possesses a plurality of hydroxyl functional groups, meeting a limitation of instant claims 5 and 6. Drohan et al. does not describe the supplemented chitin hydrogel using the terminology of an inclusion compound, however a polysaccharide cast, mixed or dispersed in a chitin hydrogel matrix meets this description. Drohan et al. specifically disclose complexes of chitin and ciproflaxin (melting point 255 - 257 °C), tetracycline (melting point 170 - 173 °C) and ampicillin (melting point 208 °C) (column 31, lines 42-45, meeting a limitation of the melting point limitation of instant claim 1.

Drohan et al. does not specifically disclose the chitin to be β-chitin or the chitin complex comprising an intercalation compound (instant claim 1).

Kim et al. teaches β-chitin will be a good candidate material for uses in medical implant devices, wound dressings, drug delivery, and so on (page 2368, left column, lines 13-17). Kim et al. teaches permeation of water into the crystalline region of the β-chitin molecule was more easily allowed than that of α-chitin (page 2370, right column, paragraph 2). Kim et al. teaches this swelling behavior of β-chitin suggests that it would

be a good candidate for biomedical application using hydrogel types (page 2371, left column, paragraph 2).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the invention of Drohan et al. with the teaching of Kim et al. of the specific chitin β-chitin. Drohan et al. discloses chitin is a material that is biocompatible and naturally resorbed by the body, and has been previously used for sustained drug release, bone induction and hemostasis (column 1, lines 20-22). Drohan et al. discloses "Any chitin or its derivative, such as a commercially available chitosan, may be used in some embodiments of this invention. For these uses, such as localized drug delivery, the particular composition of the selected chitin or derivative is not critical as long as it functions as desired." (column 18, lines 56-60) Kim et al. teaches β-chitin will be a good candidate material for drug delivery, providing motivation for one of ordinary skill in the art at the time of the invention to combine the invention of Drohan et al. with the teaching of Kim et al. of β-chitin.

Response to Applicant's Remarks:

Applicant's Remarks, filed 12 Jan 2009, have been fully considered and found not to be persuasive.

Applicant notes that Kim et al. teaches only the permeation of water into the crystalline region of the β-chitin and Kim et al. does not teach the permeation of any compound other than water into the crystalline region of the β-chitin. However, Kim et al. teaches this swelling behavior of β-chitin suggests that it would be a good candidate for biomedical application using hydrogel types (page 2371, left column, paragraph 2).

Drohan et al. teaches "supplemented" to mean the supplementary compound, or guest compound, may be mixed with the chitin components in liquid form prior to hydration or added to the hydrogel as the matrix sets up after hydration (column 12, lines 24-26) and a "matrix" to mean the structural properties or architecture of a solid or semi-solid (including a hydrogel) in which other components may be cast, mixed, dispersed or dissolved (column 12, lines 55-58). One of ordinary skill in the art would understand from the teaching of Drohan et al. that the water in a supplemented hydrogel as taught by Drohan et al. acts as the solvent to carry the supplementary compound into the matrix wherein said supplementary compound is cast, mixed, dispersed or dissolved so as to act as a guest compound. Therefore it is the combined teaching of Drohan et al. in view Kim et al. that is relied upon to render obvious the instantly claimed invention. It is found that the teaching of Kim et al. as applied to the teaching of Drohan et al., teaches to one of ordinary skill in the art that the permeation of water into the crystalline region of the β-chitin would act as the solvent to carry any supplementary compound, or guest compound, into said crystalline region of the β-chitin as in the biomedical art of supplemented hydrogels.

Conclusion

No claim is found to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-

3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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